Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Protocol summary

Study aim

comparison effect of Ondansetronand Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Design

This study is clinical trial and double blind. 114 patients candidate abdominal hysterectomy referring to Taleghani Hospital of Arak admitted. We divide patients randomly to three groups (Ondonestrone, haloperidol, and Dexmedetomidine) by simple randomization method.

Settings and conduct

This study is clinical trial and double blind. 114 patients undergoing abdominal hysterectomy referring to Taleghani Hospital of Arak admitted . Patients assigned randomly to three groups by simple randomization method.The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients are candidates for abdominal hysterectomy, ASA class I and II, no history of psychiatric and psychology, the absence of Parkinson's disease, motion sickness or chemotherapy history, patients under general anesthesia, patients aged 35-60 years, maximum surgical duration 150 minutes Exclusion criteria: surgical duration more than 150 minutes

Intervention groups

In the Haloperidol group, 2 milligrams of Haloperidol are given intravenously (equivalent to one milliliter) , In the Ondansetron group, 4 milligrams of Ondonestrone are given intravenously (equivalent to 1 milliliter) and In the Dexmeditomidine group, 1 micro gram in kilogram of Dexomedetomidine is given intravenously (equivalent to 1 milliliter).

Main outcome variables

vomiting score, nausea, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N84**
Registration date: **2018-08-29, 1397/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-29, 1397/06/07**
Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-08, 1396/07/16

Expected recruitment end date

2018-10-08, 1397/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Public title

comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients are candidates for abdominal hysterectomy ASA class I and II No history of psychiatric and psychology The absence of Parkinson's disease, motion sickness or chemotherapy history Patients under general anesthesia Patients aged 35-60 years Maximum surgical duration 150 minutes

Exclusion criteria:

Surgical duration time more than150 minutes

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.ARAKMU.REC.1396.111

Health conditions studied

1

Description of health condition studied

abdominal hysterectomy

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

Vomiting score

Timepoint

4 and12 and 24 hours after surgery

Method of measurement

Vomitting score

2

Description

Nausea

Timepoint

After surgery

Method of measurement

Clinical observation

3

Description

Sedation

Timepoint

In recovery

Method of measurement

Ramsy score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the Haloperidol group, 2 milligrams of Haloperidol are given intravenously (equivalent to one milliliter).
Category
Treatment - Drugs

2

Description
Intervention group: In the Ondansetron group, 4 milligrams of Ondonestrone are given intravenously (equivalent to 1 milliliter).
Category
Treatment - Drugs

3

Description
Intervention group: In the Dexmeditomidine group, 1 micro gram in kilogram of Dexomedetomidine is given intravenously (equivalent to 1 milliliter).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr Maryam Shokrpour
Street address
Taleghani hospital, Emam Khomeini street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
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Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
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arjmandzadegan@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Maryam Shokrpour
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr Alireza Kamali

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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student of medicin

Latest degree
Medical doctor

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
When we publish article in journal.

When the data will become available and for how long
After the article is published

To whom data/document is available
researcher in university

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
dr Alireza Kamali

What processes are involved for a request to access data/document
They have to write letters to the professors and the university

Comments